

**REMARKS:**

Applicants respectfully request reconsideration and withdrawal of the outstanding Office Action rejections based on the foregoing amendments and following remarks. Claims 29, 31, 48, 49, 51, 53, and 54 have been amended, claim 35 has been cancelled, and new claims 55-56 have been added. No new matter has been added.

Information Disclosure Statement

The Examiner states that foreign references disclosed in the Information Disclosure Statement (IDS) dated November 24, 2004 have not been considered because copies of the references were not submitted. Applicants submit that no IDS was filed on November 24, 2004 because this application only entered the U.S. national phase on September 25, 2006, on which day an IDS, listing references cited in the International Search Report was also filed. Copies of all of the references cited in that IDS are submitted herewith.

Response to Rejections under § 112

Claims 29-52 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner asserts that the claims are not clear because it is not clear how the composition subsections are different from each other. The Examiner asserts that the metes and bounds of the claimed composition are not clear as a broad reading of the claims suggests that subsections a), b), and c) can be the same. Applicants submit that claim 29 has been amended to limit the composition so that the components are not the same. Applicants submit that, as amended, the subsections cannot all be

the same and that the metes and bounds of the composition are clear. Applicants respectfully request that the rejection be withdrawn.

#### Response to Rejections under § 102

Claims 29, 36-38 and 48-52 were rejected under 35 U.S.C. § 102(b) as being anticipated by Raaf et al. (U.S. 4,397,837). The Examiner asserts that Raaf discloses two-part compositions, one comprising a soluble calcium and the second comprising a soluble phosphate, which may be a gel, a paste, or a solution (col. 2, lines 43-44), for the remineralization or inhibiting demineralization of teeth. The Examiner asserts that Raaf discloses thickeners (col. 4, line 13), including carboxymethylcellulose and caragheenate, as well as glycerol (examples) and asserts that gelatin is a thickener (citing to U.S. 4,474,750) and that gelatin was used in Raaf. Applicants submit that independent claim 29, as amended, are not anticipated by Raaf. Claim 29 has been amended to recite that, besides apatite or dentine, fluoroapatite can also be grown on teeth. Written description support for this amendment can be found, for example, on page 4, line 25 of the specification. Further, the subject matter of claim 35, that the alkaline medium comprises calcium ions, has been incorporated into claim 29. The subject matter of claim 31, that the second gel is not only free of phosphate ions but also free of calcium ions, has also been incorporated into claim 29. Finally, the subject matter of claim 50, that the fourth component of the composition is a solution containing calcium ions, has been incorporated as well. No new matter has been added.

Raaf et al. disclose a process for *remineralizing* dental enamel by contacting first ions and second ions separately with the tooth material. See claim 1 of Raaf. The

different ions are applied to the tooth's surface in the form of toothpastes via tooth brush (Raaf; Examples 1 and 2), by rinsing the mouth with two different mouthwashes (Raaf; Example 3) or by chewing gum or by eating a "bonbon pair" (Raaf; Examples 4-5). In any case the system according to Raaf is characterized by application of mechanical stresses in all proposed applications (chewing stress, tooth brush activity, etc.). Accordingly, no morphology of the apatite according to the invention are obtainable in Raaf, because none of the biomimetic main principles, namely self-assembly of the locally separated reactive ions in specifically designed bio-organic gels, exclusion of external stress/disturbances, and long exposure times are considered by Raaf. Thus, according to the present invention, the second layer is free of phosphate ions so that the second layer forms a protection layer between the first (phosphate containing) and the third (calcium containing) layer, thereby separating the phosphate ions from the calcium ions, which results in a self-assembly of apatite crystals.

Applicants submit that Raaf does not disclose a composition containing an alkaline medium **and** a solution containing calcium ions. The Examiner admits that there is no specific mention of an alkaline medium in Raaf on page 8, 1<sup>st</sup> paragraph of the Office Action. Furthermore, the Examiner has acknowledged that Raaf did not anticipate the subject matter of claims 31 and 35. Because this subject matter has now been incorporated into claim 29, Applicants submit that Raaf does not disclose all of the features of the claimed invention. Accordingly, Applicants submit that for at least these reasons, the anticipation rejection has been overcome and respectfully request that the rejection be withdrawn.

Response to Rejections under § 103

Claims 30-35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Raaf in view of DiGiulio (U.S. 4,080,440). The Examiner acknowledges that Raaf does not disclose an alkaline medium, but asserts that DiGiulio discloses that use of a slightly alkaline supersaturated calcium phosphate solution causes some degree of enamel remineralization (col. 1, lines 45-48) and the use of a 10% NaOH solution in tooth paste preparation (col. 8). Thus, the Examiner asserts that the combination of Raaf and DiGiulio render obvious the use of an alkaline medium comprising NaOH and calcium phosphate in a composition for remineralizing tooth material. The subject matter of claim 35 has been incorporated into claim 29 and claim 35 has been cancelled.

Applicants submit that both Raaf and DiGiulio are directed to two-component, single-phase systems, whereas the presently claimed composition is distinguished from the cited art because it is a multi-component, multi-phase system, requiring an alkaline medium comprising calcium ions, a first gel comprising gelatin and phosphate ions, a second gel, which is free of phosphate ions and calcium ions, capable of covering a first layer of said first gel with a layer of the second gel, and a solution containing calcium ions. Accordingly, Applicants submit that because independent claim 29 is not anticipated by Raaf for the reasons stated above, and because DiGiulio does not remedy the deficiencies of Raaf, claims 30-34, depending from claim 29 are not rendered obvious by the combination of Raaf and DiGiulio. Accordingly, Applicants respectfully request that the rejections be withdrawn.

Further, DiGiulio discloses that the pH of both portions of the toothpaste should be "less than about 5." See col. 7, lines 17-32. However, claim 33, which depends from

claim 29, requires that the alkaline medium have a pH of 7.1 to 14. Thus, Applicants submit that DiGuilio teaches away from the subject matter of claim 33. Applicants respectfully request that the rejection of claim 33 be withdrawn for this additional reason, even if the above arguments are not found to be persuasive.

Claims 38 and 51 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Raaf in view of Wiedemann (U.S. 6,010,684). The Examiner acknowledges that Raaf does not disclose the pH of the compositions, but asserts that Wiedemann discloses two part compositions comprising phosphate ions in one part and calcium ions in the second part for the remineralization of teeth (col. 1, lines 11-20). The Examiner contends that Wiedemann discloses that the phosphate part has a pH of 3.0 to 6.5 and the calcium part has a pH of 3.0 to 7.0, so that, when combined, the combination yields a pH from 2.0 to 5.0 (col. 1, lines 59-67) resulting in deep remineralization. The Examiner asserts that this disclosure, in combination with Raaf, renders claims 38 and 51 obvious because it would have been obvious to have adjusted the pH of each component in Raaf motivated by the desire to obtain the deep remineralization effects shown in Wiedemann. Applicants submit that both Raaf and Wiedemann are directed to two-component systems, whereas the presently claimed composition is a multi-phase system requiring an alkaline medium comprising calcium ions, a first gel comprising gelatin and phosphate ions, a second gel, which is free of phosphate ions and calcium ions, capable of covering a first layer of said first gel with a layer of the second gel, and a solution containing calcium ions. The Examiner has acknowledged that Raaf does not disclose or suggest that the alkaline medium comprises calcium ions or that the second

gel is not only free of phosphate ions but also free of calcium ions. Because Wiedemann does not remedy the deficiencies of Raaf, claims 38 and 51, depending from claim 29 are not rendered obvious by the combination of Raaf and Wiedemann. Accordingly, Applicants respectfully request that the rejections be withdrawn.

Claims 39-47 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Raaf in view of Barth et al. (U.S. 2007/0154411). The Examiner acknowledges that Raaf does not disclose fluoroapatite or particle size, but asserts that Barth discloses using fluoroapatite, hydroxyapatite, calcium hydrogen phosphate, and calcium fluoride as remineralization-promoting agents, in amounts from 0.1 to 10% by weight (paragraphs [0061] and [0062]) and particle size from 1 to 200 microns (paragraph [0042]). The Examiner asserts that it would have been obvious to use the remineralization promoting components of Barth in the compositions of Raaf. Applicants submit that the presently claimed composition requires an alkaline medium comprising calcium ions, a first gel comprising gelatin and phosphate ions, a second gel, which is free of phosphate ions and calcium ions, capable of covering a first layer of said first gel with a layer of the second gel, and a solution containing calcium ions. The Examiner has acknowledged that Raaf does not disclose or suggest that the alkaline medium comprises calcium ions or that the second gel is not only free of phosphate ions but also free of calcium ions. Because Barth does not remedy the deficiencies of Raaf, claims 39-47, depending from claim 29 are not rendered obvious by the combination of Raaf and Barth. Accordingly, Applicants respectfully request that the rejections be withdrawn.

Claims 29-38 and 48-52 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ebner (DE 3303 937) in view of Singh (U.S. 2003/0152528) and further in view of DiGiulio. The Examiner asserts that Ebner discloses gel compositions using phosphate gelatinized solutions and calcium gelatinized solutions. The Examiner acknowledges that Ebner does not disclose a second gel that is absent of phosphate or fluoride ions, but asserts that Singh discloses hydrogel compositions for whitening teeth, separated into separate layers depending on their reactivity to one another, and having one or more additional hydrogel or non-hydrogel layers that are not compatible with the whitening agent (paragraph [00116]). The Examiner further asserts that these references disclose media containing calcium ions which can be interpreted as an alkaline medium, even though specific mention of alkaline medium is absent.

Applicants submit that the components used in the presently claimed composition are not incompatible with one another as in Ebner, Singh, and DiGiulio. For example, Ebner discloses placing caps containing a phosphate solution on teeth for some time and then placing a cap containing calcium solution on teeth. Thus, Ebner discloses applying the solutions to teeth separately, i.e., not as a composition or layer structure, but as separate solutions. The combination of Singh, DiGiulio, and Ebner would not have made it obvious to one of ordinary skill to produce the presently claimed composition because the cited references do not consider the biomimetic principles of the present invention, namely 1) an alkaline medium for pretreatment, 2) locally separated reactive ions in a bio-organic gel, 3) exclusion of external

stress/disturbances, and 4) mineralization conditions that bring about the formation of tooth enamel-like substances. The combination of Singh and Ebner does not

It is unclear how one of ordinary skill would go about combining the disclosures of Ebner, DiGiulio, and Singh to arrive at a useful product. The metastable aqueous solution of DiGiulio, comprising both phosphate and calcium ions is contrary to the system of Ebner, which requires keeping the calcium and phosphate ions separated until after application and incubation for some time on teeth. One could imagine using the separate gelatin layers containing whitening and other active ingredients of Singh in one or both of the caps of Ebner, or perhaps using the separate application by caps method of Ebner to apply the composite active layers of Singh for teeth whitening, or even mixing up calcium and phosphate ions in each gel, based on Singh, or each cap, according to Ebner, 5 minutes before application as suggest by DiGiulio. It is clear that it is beyond mere routine or obvious modification to modify Ebner according to the disclosures of Singh and DiGiulio, taking individually, or in combination, to eliminate the two-phase, time-guided solution application process of Ebner and to instead somehow arrive at the presently claimed composition. Even a hypothetical picking and choosing of particular components and steps in an attempt to arrive at the presently claimed composition leads to a plethora of possibilities and difficulties. Thus, Applicants submit that the purported combination of references is improper and unworkable because there is no clear and obvious way that the combination of the cited references would produce the presently claimed composition and that one of ordinary skill in the art, motivated by a desire to inhibit the phosphate or calcium ion from reacting with additional additives,



would have become mired in the inconsistent and incompatible disclosures of the cited references.

Applicants further submit that, even if one were to try to combine the disclosures of Ebner, Singh and DiGiulio, such a combination would still not render the present claims obvious. Ebner does not disclose using a second gel that is free of phosphate and calcium ions and Singh does not suggest incorporating such a layer. Rather, Singh discloses having a layer containing whitening active ingredient and additional layers containing other actives that are not compatible with the whitening agent. DiGiulio also does not remedy this deficiency. Thus, the combination is clearly deficient for this reason. Further, none of Ebner, Singh, or DiGiulio discloses an alkaline-calcium medium component used to pretreat as required by the present invention or the additional calcium solution component. While DiGiulio states that the prior art suggested using slightly alkaline calcium phosphate in a cap applied to roughened teeth for several days to effect some degree of remineralization (col. 1, lines 41-48), there is no suggestion to use an alkaline-calcium medium in the composition as a pre-treating component separate from, and in addition to, active and inactive gel components. Accordingly, Applicants submit that even if the combination of references was made, it would not render the presently claimed composition obvious. Applicants respectfully request that the rejections be withdrawn.

Moreover, claim 33 is not rendered obvious by the disclosure in DiGiulio for the reasons stated above and Applicants respectfully request that the rejection of claim 33 be withdrawn for this additional, independent reason.

New Claims

New claims 55 and 56 have been added to define further embodiments of the invention. Written description support for these claims can be found on page 4, lines 10-20 and on page 6, lines 10-19. No new matter has been added.

Conclusions

In view of the above amendments and remarks hereto, Applicants believe that all of the Examiner's rejections set forth in the June 18, 2010 Office Action have been fully overcome and that the present claims fully satisfy the patent statutes. Applicants, therefore, believe that the application is in condition for allowance.

The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

The Examiner is invited to telephone the undersigned if it is deemed to expedite allowance of the application.

Respectfully submitted,

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